IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: Ethicon Wave 3 cases listed in Exhibit A to Plaintiffs' Motion	

PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION TO EXCLUDE THE GENERAL CAUSATION OPINIONS OF DEFENSE EXPERT MICHAEL P. WOODS, M.D.

Plaintiffs respectfully submit this Reply Brief in support of their motion to exclude the opinions of Michael P. Woods, M.D. Plaintiffs moved to exclude Dr. Woods's opinions in Wave 1, and then adopted that motion in Wave 3. Defendants filed a substantive response, so Plaintiffs are filing this reply to address issues raised by the Defendants' brief and by this Court's order regarding Plaintiffs' Wave 1 motion.

First, this Court should reject Defendants' efforts to reverse this Court's decisions on particular issues in Wave 1. In discussing Dr. Woods's personal complications rates, which are supported by absolutely no data, this Court wrote that "Dr. Woods's estimated complication rates lack any vestige of a scientifically-applied methodology." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4582231, at *3 (S.D. W. Va. Sept. 1, 2016). Nothing in Defendants' latest brief rehabilitates Dr. Woods's methodology. The brief makes the same claim that was made before, that Dr. Woods's made-up rates are consistent with the rates in the literature. Even if true, that fact does not change that there is zero support for the complication

rates that Dr. Woods asserts from his own practice. In addition, the Court should again conclude that Dr. Woods is not qualified to opine as to the adequacy of the information in the IFU.

Defendants' brief, and the Court's prior order, also raise issues regarding the scope of Plaintiffs' arguments. Plaintiffs' argument seeks to exclude all three aspects of Dr. Woods's design-based opinion, including the assertions that the TVT and TVT-O are reasonably safe for their intended use, and that the benefits outweigh the risks. While these are not—as the Court recognized—design process opinions, they are opinions that the design of the TVT was not defective. So, Plaintiffs' argument is that Dr. Woods's complete lack of knowledge as to design processes, and lack of support for an opinion based on his personal practice, leave Dr. Woods without the necessary knowledge to opine as to whether the TVT and TVT-O were defectively designed.

The other "scope" issue relates to Dr. Woods's opinions about what label information physicians already know. As with Dr. Woods's other warnings opinions, there is simply insufficient support for this opinion, so it should be excluded. Further, to the extent that the learned intermediary doctrine may command examination of that issue in a particular case, the relevant inquiry will be whether the **treating physician** knew about the risks at issue.

This Court, therefore, should exclude the entirety of the opinions stated on Pages 19 and 84 of Dr. Woods's expert report, regarding product design and warnings.[1]

[1] As recited in Plaintiffs' initial motion, these opinions are: "TVT and TVT_O are Reasonably Safe for its [sic] Intended Use, the Benefits Outweigh the Risks, and Complications are Acceptably Low Compared to Alternative Procedures." And, "The TVT and TVT-O IFUs Adequately Warn of the Risks Associated with the Products." (Expert Report of Michael Woods, Ex. C to Dkt. No. 2041, at pp. 19, 84). Where applicable, Plaintiffs will cite to documents filed with their original motion to avoid overburdening the Court with repeat exhibits.

ARGUMENT

I. Dr. Woods's lack of knowledge as to what factors go into the design of a medical device demonstrate that he does not have the knowledge base needed to opine about whether Ethicon's products are defectively designed. His unsupported complication rates further support that conclusion.

Dr. Woods's primary opinion is divided into three parts, all of which relate to product design. He asserts:

> TVT and TVT_O are Reasonably Safe for its [sic] Intended Use, the Benefits Outweigh the Risks, and Complications are Acceptably Low Compared to Alternative Procedures.[2]

The Court has already excluded the third part of that opinion, regarding complication rates, and should do so again, as discussed below. The Court previously interpreted Plaintiffs' criticisms of Dr. Woods as attacks only on his ability to opine as to design processes. It was an understandable conclusion, given the crux of Plaintiffs' arguments, but Plaintiffs will take this opportunity to clarify their position.

The first two opinions—that the TVT and TVT-O are reasonably safe for their intended uses, and that their risks outweigh their benefits—derive from tests used by courts to determine whether the design of a product is defective. Ethicon's arguments focus largely on Plaintiffs' citation to the *Winebarger* opinion, in which an expert's design process opinions were excluded. *See Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222 (S.D. W. Va. Apr. 24, 2015). The ruling may be slightly distinguishable because the issue there related specifically to design process opinions. But the Court's message remains important here: that "[w]ithout any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures from the norm; (2) not

[2] Woods Report, Ex. C to Dkt. No. 2041, at 19.

followed by BSC; or (3) lacking in any way." *Id.* at *14. Here, Dr. Woods boasted that he "absolutely" did not rely on any internal documents in forming his opinions.[3]

Not only did Dr. Woods fail to review Ethicon's documents, but he also showed a complete lack of knowledge as to design processes, and even as to the purpose of design principles. He did not review the design history file for the TVT before offering opinions—nor did he seem to know what it was.[4] Dr. Woods also could not explain what a failure modes and effects analysis is, or what the purpose of it is. (*Id.* at 99:25-100:7). In addition, Dr. Woods did not know what a DDSA is.[5] A DDSA is also an important component of the design process. The letters stand for "Device Design Safety Assessment."[6] Part of the DDSA form lists and rates hazards associated with the product.[7]

In failing to consider the information used by those designing the product—including the concerns about potential hazards that were identified in the beginning—Dr. Woods ignored important information that would be necessary to developing a reliable opinion about the safety and efficacy of the products at issue.

Essentially, Dr. Woods's opinions about safety are derived from his own practice and from his literature review. While that combination could in some cases form the foundation of a reliable opinion, here both sides of that analysis are infirmed. Dr. Woods relies on his clinical experience, but as the Court previously recognized, he has no support whatsoever for the assertion that his personal complication rates mirror what he sees in the literature. Second, while he has studied the scientific literature, Dr. Woods's lack of understanding on certain key issues

[3] Woods TVT Dep., Ex. D to Dkt. No. 2041, at 15:6-18.
[4] *Id.* at 99:4-16.
[5] *Id.* at 100:16-20.
[6] Charlotte Owens Dep., Ex. F to Dkt. No. 2041, at 497:20-23.
[7] *Id.* at 498:20-24.

regarding design creates doubt as to whether he can actually analyze the literature, rather than simply parroting what it says.

Regarding complication rates, Dr. Woods's opinions are purely speculation, as demonstrated by his deposition.

> Q. Okay. And when you looked and you put numbers in your expert report of 1 percent erosion rate, 2 to 3 reoperation rate, that's all coming from your head, correct?
>
> A. My data closely reflects the data that's out there, yes.
>
> Q. That wasn't my question. All of those numbers in your report came from your mental estimates as opposed to looking at any hard data or numbers to make those determinations; is that accurate?
>
> A. I would say that that is reasonably accurate.[8]

Dr. Woods further described his estimates as "a ballpark figure that is probably pretty close."[9]

Based on that testimony, this Court concluded that "Dr. Woods's estimated complication rates lack any vestige of a scientifically-applied methodology." *In re: Ethicon*, 2016 WL 4582231, at *3. Thus, he does not use a reliable methodology in deriving opinions about the safety of the TVT and TVT-O from his clinical practice.

Dr. Woods's testimony also casts doubt about the reliability of his literature review. A physician with some understanding of the design process could critically analyze the literature, but given Dr. Woods's complete lack of understanding as to design processes, it seems unlikely that he could do anything more than summarize the complication rates as stated the literature, as was done on his behalf in Ethicon's response brief.[10]

For these reasons, the Court should first re-affirm its decision preventing Dr. Woods from testifying as to his personal complication rates. Ethicon's argument that his rates match the

[8] *Id.* at 148:17-149:4.
[9] *Id.* at 219:11-18.
[10] *See* Response at 6-7.

literature is the same argument that Ethicon made last time, and it does not change that there is **zero** support for Dr. Woods's personal rates. The Court should also either grant the motion as to design process opinions or once again deny it as moot—so long as Dr. Woods is unable to give such opinions. *In re: Ethicon*, 2016 WL 4582231, at *3. Finally, the Court should conclude that Dr. Woods does not have a reliable foundation to opine as to the safety and efficacy of Ethicon's devices—issues that are essential to a design defect inquiry under the laws of most states—due to his lack of knowledge regarding design processes and the lack of support for his opinions derived from his clinical practice.

II. The Court should once again preclude Dr. Woods from giving opinions about warnings, and should reach the same conclusion as to opinions about the information that physicians would already know.

This Court previously held that Dr. Woods was not qualified to opine about the sufficiency of Ethicon's warnings. Specifically, this Court wrote: "Dr. Woods does not possess the additional expertise to offer expert testimony about what an IFU should or should not include." *In re Ethicon*, 2016 WL 4582231, at *3. The basis for that conclusion is laid out in the initial motion, which was adopted for Wave 3. Notably, he admitted that he is not an expert in product warnings.[11]

In addition, Dr. Woods has not presented a reliable methodology for reaching any conclusions about the sufficiency of Ethicon's warnings. His entire treatment of the topic in his expert report is approximately one page long and cites to no authority.[12]

The remaining issue is whether Dr. Woods may opine about whether certain warnings proposed by Plaintiffs cover issues that are already known to physicians. The Court expressly declined to rule on this issue in Wave 1. *In re Ethicon*, 2016 WL 4582231, at *3 n.2. The Court

[11] Woods TVT Dep., Ex. D to Dkt. No. 2041, at 93:12-24.
[12] Woods Report, Ex. C to Dkt. No. 2041, at pp. 84-85.

should also exclude such opinions for two reasons. First, there is again simply no support in Dr> Woods's report for the assertion that certain warnings were unnecessary. The report does not address specific proposed warnings or explain why they were unnecessary. The report simply states that "[c]omplications associated with stress urinary incontinence surgeries are well-known and obvious to pelvic floor surgeons performing those types of procedures."[13] There is no foundation for that opinion, and the opinion is not tied into the Instructions for Use at all. It simply claims that complications were well known, with no further support.

Ethicon argues that the learned intermediary doctrine is a basis for allowing this testimony. But that argument misses the point of the learned intermediary doctrine. When it applies, the doctrine raises an issue as to what the **implanting surgeon** knew. It is a causation issue. Dr. Woods's speculation as to what most surgeons would have known at the time of the implant is simply not relevant.

CONCLUSION

For the reasons stated above, and the reasons stated in Plaintiffs' initial memorandum, the Court should preclude Dr. Woods from giving any opinions about product design or product warnings. Because all of his opinions related to those two areas, he should be excluded entirely from testifying.

Dated: October 21, 2016

[13] Woods Report, Ex. C to Dkt. No. 2041, at p. 84.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on October 21, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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